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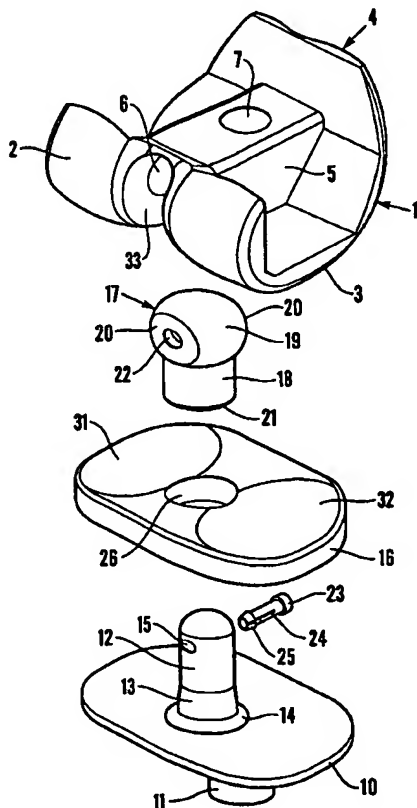
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(54) Title: **LINKED CONDYLAR TOTAL KNEE REPLACEMENT**



(57) Abstract: A knee prosthesis is disclosed comprising a femoral component (1) having condylar bearing surfaces (2, 3) and a tibial component (10) having bearing surfaces (16) for receiving the condylar bearing surfaces (2, 3), the femoral (1) and tibial (10) components being linked together by a post (12) which is secured at a first end to the tibial component (10) and at the opposite end is received in an intercondylar housing (5) of the femoral component (1), said opposite end of the post (12) having surfaces which permit relative rotational movement of the post (12) within the housing (15), but prevents the femoral component (1) separating from the tibial component (10). The advantage of the prosthesis is that it combines the bone-preserving characteristics of the constrained condylar type of prosthesis with the stability characteristics of a rotating hinge.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

LINKED CONDYLAR TOTAL KNEE REPLACEMENT

Background

This invention relates to a linked condylar knee prosthesis.

There are several different types of knee replacement in use today, for the treatment of arthritis of the knee and other conditions. The most commonly used design is the total condylar replacement. In this design, the prosthesis replaces the femoral-tibial and the patello-femoral bearing surfaces of the natural knee. The tibial component consists of two parts, a metal tray to cover the upper tibia, with a plastic bearing surface, articulating with the Femoral Component, fixed to the metal tray. A plastic component is frequently used to resurface the patella. In all versions of this design, the anterior cruciate is not retained, its function being replaced by dishing of the plastic bearing surface. In one version, the posterior cruciate is retained. In another version, the posterior cruciate is resected and its function replaced by increased dishing or by an intercondylar cam. The latter design is usually referred to as a posterior stabilised, or posterior cruciate substituting. Most cases of arthritis of the knee can be treated with one of these types of condylar replacement, and the results have a high success rate at up to 10 years and even beyond.

When the arthritis is limited to only one of the pair of bearing surfaces, such as the medial side in varus osteoarthritis, and both of the cruciate ligaments are viable, it is sometimes considered preferable to use a compartmental knee replacement, generally called a "uni". When inserted correctly, the functional results closely resemble normal. Such knees are often used in the younger and more active

patients because of the very limited amount of bone and tissue removal, and the incisions can be much smaller than for conventional total condylar replacement. Another consideration for the younger active patients is the wear of the bearing surfaces. In order to reduce the wear of the bearing surfaces, the femoral-tibial bearing can be made to be conforming which minimises the contact stresses. However, in order to allow the rolling and sliding movements, the plastic bearing needs to be mobile, such that it slides and rotates on a polished upper surface of the tibial tray. Such designs are called mobile bearing knees. These can be made in either the compartmental form, or as a total condylar type.

At the other extreme, there is a requirement for the treatment of knees involving one or more of the following conditions: severe bone loss or deformity, severe instability, gross deformity with non-viable soft tissues, bone tumour where the distal femur or proximal tibia requires resection, failed knee replacements of various types. In general, it can be said that this category includes those knees for which a total condylar replacement would be inadequate, particularly in terms of providing the required stability. In this case, a knee replacement which provides the appropriate amount of constraint is required. One type of knee which has been used for such cases is a variant of a total condylar called the constrained condylar. As the name implies, the design incorporates all of the design characteristics of a total condylar, but the Femoral Component includes a housing located in the intercondylar region, into which a post projecting from the centre of the tibial bearing component is located. This combination provides varus-valgus stability, partial anterior-posterior

stability, and partial rotational stability. An advantage of the design is that the bone resection required for insertion is little greater than that for a total condylar, while the intercondylar region only requires squaring off. However, the limitations are that there is no limit to hyperextension, there can be inadequate anterior-posterior stability in some cases, and the varus-valgus stability is limited in some designs by the strength and stiffness of the tibial plastic post. When greater stability and strength is required, some type of linked total knee is required.

The simplest type of linked total knee is a fixed hinge, and indeed this type of knee was already being used in many cases as early as the 1950's. These early designs were unsatisfactory for a number of reasons. However, more recently, the design and the surgical technique have improved to the extent that the success rate of hinges approaches that of total condylars, even taking into consideration the more severe cases which are dealt with. There are three disadvantages of fixed hinges however. Firstly, the degree of bone resection required is large, about 25 mm from the distal femur and 10 mm from the proximal tibia. Secondly, intramedullary stems of length about 150 mm, rigidly fixed to the bones, are required for fixation. Thirdly, the motion is restricted to that of a hinge with no provision for internal-external rotation or other movements.

However, it would be an advantage if the bone-preserving characteristics of the constrained condylar type could be combined with the stability characteristics of a rotating hinge. This invention discloses a solution which seeks to accomplish that. Such a design would have a much wider application than either type as it could be

used for all of the indications combined. Another advantage of the concept is that it would remove the uncertainty as to which type of knee to use, a constrained condylar type or a linked type. The proposed design could be used in all circumstances.

According to one aspect of the present invention there is provided an intercondylar knee prosthesis which comprises a Femoral Component having condylar bearing surfaces and a tibial component having bearing surfaces for receiving the condylar bearing surfaces, the femoral and tibial components being linked together by a post which is secured at a first end to the tibial component and at the opposite end is received in an intercondylar housing of the femoral component, said opposite end of the post having surfaces which permit relative rotational movement of the post within the housing, but prevents the femoral component separating from the tibial component.

The opposite end of the post may be a sphere or a cylinder or other shaped surface which permits the femoral component to undergo at least a limited degree of lateral-medial rotation, e.g. up to about $\pm 10 \rightarrow 15^\circ$, e.g. about 12° to each side of the anterior-posterior center-line.

Preferably, the post comprises a cylindrical post fixed to the tibial component mounted on the post. The plastic pivot component is fixed against rotation on the cylindrical post and is formed with spherical or cylindrical surfaces for engaging in and rotating within recesses in the intercondylar housing.

The invention will be illustrated by the following specific embodiments shown in the accompanying drawings, in which:-

Figure 1 is an 'exploded' perspective view of one embodiment of knee prosthesis in accordance with the invention;

Figure 2 is a perspective view of the embodiment shown in Figure 1 after assembly;

Figure 3A, B & C show the stages of assembly of the prosthesis; and

Figures 4A & B show posterior and lateral views of a modified prosthesis in accordance with the invention.

Description of Specific Embodiments

The components of the prosthesis are shown individually in Figure 1. The femoral component (1) is made from a metal such as cast cobalt-chrome or titanium alloy. In use, this component is affixed to the distal end of the femur which is shaped during surgery with rectangular and angular cuts so that the Femoral Component is a close fit. Component (1) replaces the normal bearing surfaces of the distal femur. The main bearing surfaces of component (1) are the lateral and medial condyles (2 & 3), which extend distally to posteriorly. These bearing surfaces transmit the forces between the femur and the tibia. At the anterior of component (1) is a patella bearing surface (4), consisting of a groove along which the patella slides as the knee is flexed and extended. In the centre of the femoral component (1) is an intercondylar housing (5), which fits within the intercondylar region of the femur, requiring only squaring off of this area in the femur in order to locate and provide space for the housing (5). The posterior region of the housing is hollowed with parallel sides. In line with the centre of curvature of the femoral condyles,

spherical surfaces are machined into the housing so that each side of the sphere creates spherical saucer-like recesses (6) on either side of the anterior-posterior (A-P) centre-line of the housing, with a spherical surface also being formed at the top of the housing. The anterior part of the housing is solid, but has a hole (7) bored into it from the top for the fitting of a femoral stem, to facilitate fixation of the femoral component into the femur. Preferably, the hole is tapered to allow for modular stems of different lengths and diameters to be fitted to the femoral component (1).

The tibial base plate (10) is made from a metal such as cast cobalt-chrome or titanium alloy. This component is affixed during surgery to the upper end of the tibia, which has been resected horizontally to accommodate the component. A spigot (11) is attached to the lower surface of the baseplate in line with the intramedullary canal of the tibia, for the purpose of attaching a stem, along similar lines to that on the femoral side. A metal post (12), preferably cylindrical, projects from the upper surface of the baseplate. This may be formed integrally with the baseplate or rigidly fixed thereto. The lower part (13) of the post is preferably conical and radiused at (14), in order to maximise its strength for horizontally directed forces applied at the top of the post. A cylindrical hole (15) passes through the top of the post in an anterior-posterior direction, the purpose being described below.

A plastic tibial bearing component (16), made from a material with high wear resistance such as ultra-high molecular weight polyethylene (UHMWPE), locates onto the tibial base plate. The bearing component is intended to lock tightly to the

base plate, e.g. using cooperating rims and undercuts on the tibial base plate and meniscal component. Post (12) projects through a hole (26) in the bearing component (16).

Mounted on the top of the post (12) is a plastics pivot component (17) made from UHMWPE. It comprises a cylindrical part (18) integral with a spherical top (19). The spherical top has flats (20) on opposite sides, such that the width across the flats is substantially the same as the diameter of the cylindrical part (18). There is a vertically oriented hole (21) along the centre of the pivot component (17) in line with the centreline of the cylindrical part, the hole being substantially the same shape and diameter as the upper part of the post on the tibial base plate. This is so that the pivot component (17) fits closely over the cylindrical upper part of post (12). Pivot component (17) has a second hole (22) for receiving and locking pin (23) extending in an anterior-posterior direction through the component, in line with the centre of the spherical surface (19).

Locking pin (23) is made from forged cobalt-chrome or titanium alloy. The material needs to be such that the two ends of the pin can be compressed, closing the slot, without permanent deformation or fracturing of the pin. Pin (23) is formed with a slot (24) and tangs (25) to snap outwardly after insertion. The diameters of the tangs and pin head of the locking pin are such that they are a clearance fit in the hole in the pivot component (17). The main cylindrical part of the pin is a sliding fit in the hole in the post (12) of the tibial base plate (10).

Assembly of components into the knee

Assembled condition of the components shown in Figure 1 is shown in Figure 2. As noted, the ends of the bones are shaped to receive the femoral component (1) and the tibial base plate (10). The plastics tibial bearing component (17) is fixed to the top of the tibial base plate. The plastic pivot component (17) is located onto the post (12) projecting from the tibial base plate. The orientation of the pivot component (17) in the fully assembled position is as in Figure 1. The pivot component (17) is held in place on the post by the locking pin (23). The spherical sides of the plastic pivot component are located within the spherical saucer-like recesses (6) in the housing of the femoral component. Likewise, the spherical top of the pivot component (17) engages against the spherical top of the housing. In the assembly, the lateral and medial metal femoral condylar bearing surfaces (2,3) locate on to the corresponding plastic tibial dished lateral and medial bearing surfaces (31,32).

It may not be immediately obvious how the assembly can be accomplished within the confines of the knee. Once the femoral and tibial components (1) & (10) are affixed to the respective bones, it may be difficult to assemble the plastic pivot component (17) on to its post and then into the femoral housing. The assembly process is described with the aid of Figures 3A, 3B & 3C. The femoral component (1) and the tibial base plate (10) are affixed to their respective bones, and the plastic tibial bearing component (16) is fixed to the tibial base plate. The knee is flexed to about 120 degrees (Figure 3A) and the tibia is pulled anteriorly. The tibial post (12)

is now anterior to the femoral component (1). The plastic pivot component (17) is slid on top of the post, in an orientation such that the plane of the flats (20) is parallel to the sagittal plane of the knee. In this orientation, when the tibia is moved posteriorly towards the femoral component, the plastic pivot component (20) slides into the slot (33) of the housing (5). It is noted that the width of the plastic pivot component across the flats is substantially the same as the width of the housing (Figure 3B) so that the pivot component (17) is a sliding fit into the slot (33). When the spherical part of the pivot component is in line with the spherical saucer-like recesses (6) in the housing, the pivot component is rotated by 90 degrees about its vertical axis. The spherical surfaces are now in engagement (Figure 3C). In order to fix the pivot component (17) into this orientation, the locking pin (23) is snapped into place. When the tangs of the pin spring outwards again, the Pin cannot disengage. The pin has a secondary purpose of fixing the pivot component (17) on the post (12) in a vertical direction.

Alternate configurations can be specified for engaging a spherical surface into a spherical recess in the housing, such that assembly is possible but disengagement is prevented. For example, in a modified embodiment as shown in Figures 4A & 4B, the top of the plastic pivot component (20) does not have the flats but has a complete spherical surface on top of the cylindrical part (12). The inside of the housing (5) in the femoral component (1), rather than having spherical recesses, has a cylindrical hole which is substantially the same diameter as the spherical top (19) drilled in from the distal end of the component to enter the spherical recesses. With the femoral

component at 90 degrees of flexion, this cylindrical hole lies horizontally. The plastic pivot component (17) can now enter from the anterior until it reaches its proper location. In order to prevent it from escaping, an arcuate-shaped component (35) made from plastic or metal is pressed into the cylindrical hole. A small shelf in the cylindrical surface in the femoral component allows this arcuate-shaped component to snap into and be held in place. The component essentially restores the shape of the femoral component to the shape in the original embodiment shown in the earlier Figures. One advantage of using an annulus is that a complete sphere can be used on the pivot component (17) which may have slightly greater strength. On the other hand, it requires an extra part (35) for which the tolerances are stringent.

Another method for locating the pivot component (17) is shown in Figure 4A. This component has a boss (36) at the lower end. The component is first assembled on the post (12). The plastic tibial bearing component (16), in lateral and medial halves, is fixed into the tibial base plate. This interaction prevents the pivot component (17) from migrating upwards, thus making it more rigid in relation to varus-valgus and hyperextension movements. The prevention of rotation could be with a locking pin through the anterior of the bearing component and into the boss.

Function of the assembled knee

When the linked knee is assembled as described above, the femoral and tibial components cannot disengage. The joint acts as a hinge point, pivoting about a traverse line through the centre of the sphere. This line is also the centre of the sagittal radius of the lateral and medial femoral condyles, so that in flexion-extension,

the condyles remain in contact and transmit the axial forces through the knee. For this to occur, it is necessary that the femoral bearing surfaces have the same radius in the sagittal plane from the distalmost point to the posterior upper limit.

Another aspect of the design is the capability for internal-external rotation about a vertical axis through the centre of the tibial post (12), that axis passing through the centre of the sphere (19). Because the surfaces in the housing are spherical, it is possible for the femoral component (1) to rotate about this vertical axis relative to the tibial component. This provides for internal-external rotation, which is an important aspect of the motion of the natural knee. Not only does it allow for more natural function, but it reduces the stresses on the fixation of the components to their respective bones. Internal-external rotation may be restricted by providing stops. However, the interaction of the condylar bearing surfaces in the dished recesses in the plastic meniscal bearing component exerts a restraining effect on such rotation and tends to bring the femoral component back to the position shown in Figure 2 in relation to the meniscal component (16), after a force tending to cause rotation is removed.

The posterior part of the femoral housing is designed to allow for a high range of flexion, such as 130 degrees. It is unlikely that a knee will reach this angle and hence the linked knee joint will not restrict the motion of any knee into which it is inserted. When the knee is brought to full extension, the larger anterior radius of the femoral condylars are designed to locate on the anterior of the plastic tibial bearing component. Anterior to the distalmost point, the radius is larger, such that a

restraint is provided to further extension. This provides that motion beyond full extension is prevented by the interaction between the femoral-tibial contact points and the action of the sphere in the housing. A few degrees of hyperextension is provided by allowing clearance at the anterior surface of the housing. In this way, the knee is brought to a stop without a sudden impact. In cases where the condylar surfaces and the corresponding dished recesses in the plastic bearing component are closely conforming (which is the preferred arrangement), the condylar surfaces may be relieved to provide recesses. This allows for maximum extension as described in WO 94/26212, the disclosure of which is specifically incorporated herein by reference.

Varus-Valgus movement between the femoral and tibial components is prevented because of the close fit between the plastic pivot component and the housing in the femoral component: this stability is a very important goal of the knee prosthesis of this invention.

It will be appreciated that in order not to cause a kinematic mismatch between the femoral-tibial bearing surfaces and the spherical surfaces in the femoral housing, when the knee undergoes the various movements described above, appropriate tolerances will need to be provided. In practice, the sphere is allowed a small amount of upward-downward movement on the post, for example, by making the hole in the pivot component slightly larger than the diameter of the diameter of the tangs and the pin head. Other methods may be adopted for providing such

tolerance, e.g., the recess (6) in the intercondylar housing can be made slightly larger than the spherical or cylindrical surface (19).

CLAIMS:-

1. An intercondylar knee prosthesis which comprises a femoral component having condylar bearing surfaces and a tibial component having bearing surfaces for receiving the condylar bearing surfaces, the femoral and tibial components being linked together by a post which is secured at a first end to the tibial component and at the opposite end is received in an intercondylar housing of the femoral component, said opposite end of the post having surfaces which permit relative rotational movement of the post within the housing, but prevents the femoral component separating from the tibial component.

2. A prosthesis as claimed in claim 1 wherein said opposite end of the post has spherical surfaces which engage in a recess in the intercondylar housing having spherical surfaces of corresponding or larger radius whereby the said opposite end of the post is trapped in said recess but is able to rotate therein.

3. A prosthesis as claimed in claim 2 wherein said opposite end of the post includes a complete or partial sphere, the diameter of which is greater than the width of the post.

4. A prosthesis as claimed in claim 2 or 3 wherein said opposite end of the post is shaped so that its width in one axial plane is such that it can pass through a slot in the intercondylar housing leading into said recess, but its width in a second axial plane is larger such that it cannot pass through said slot, and wherein said opposite end is capable of rotation after passage through the slot and fixing relative

to the tibial component when located in said recess, so as to trap the post in the femoral intercondylar housing.

5. A prosthesis as claimed in claim 4 wherein said opposite end of the post comprises a head which is spherical or cylindrical and has flattened sides to permit entry into said slot, said head being rotatably mounted on a core and having associated fixing means for fixing the head on the core when the head is in the desired orientation on the core.

6. A prosthesis as claimed in claim 5 wherein the fixing means comprises a pin which is insertable through aligned holes in the head and core.

7. A prosthesis as claimed in claim 1 wherein said opposite end of the post has spherical surfaces and is received within a recess in the intercondylar housing which is cylindrical and has a diameter corresponding to the diameter of the spherical surfaces, the opposite end of the post being trapped in said recess by an arcuate shaped locking member which is pressed into the recess.

8. A prosthesis as claimed in any one of the preceding claims in which said opposite end of the post comprises a plastic component.

9. A prosthesis as claimed in any one of the preceding claims in which the tibial component includes a plastics meniscal bearing component which is supported on a tibial base plate.

10. A prosthesis as claimed in claim 9 in which the meniscal component is fixed on the tibial base plate.

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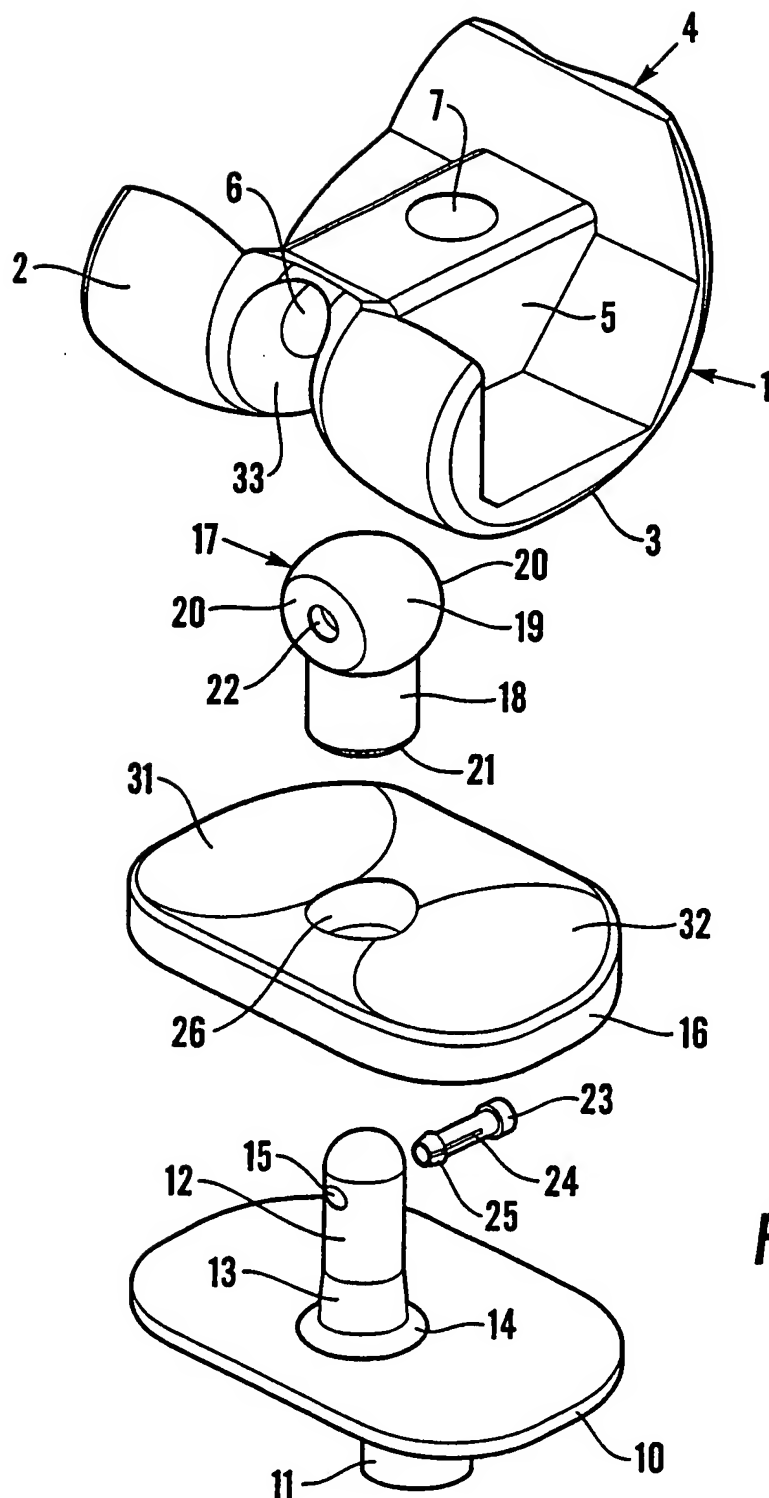


Fig. 1

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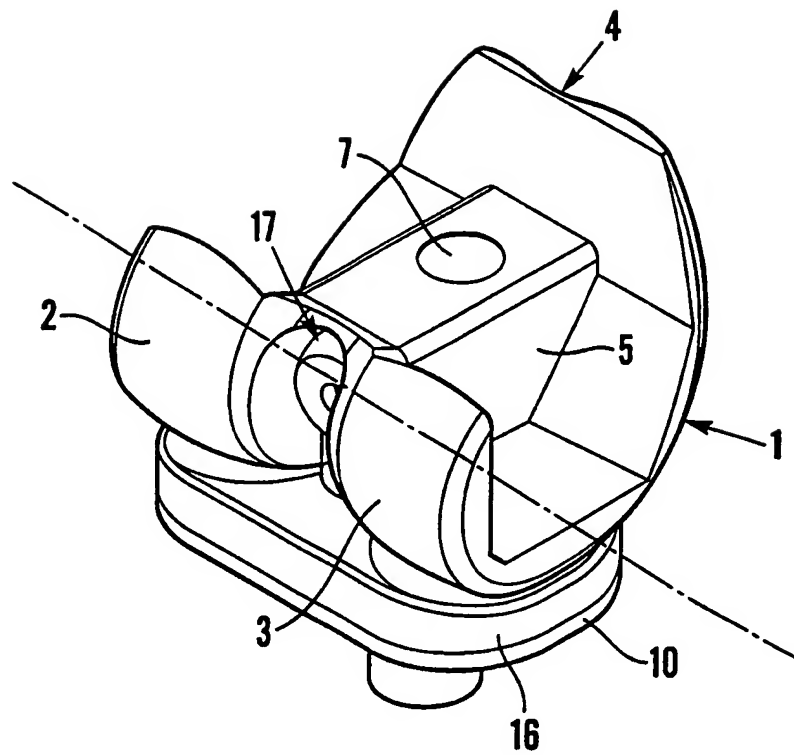


Fig. 2

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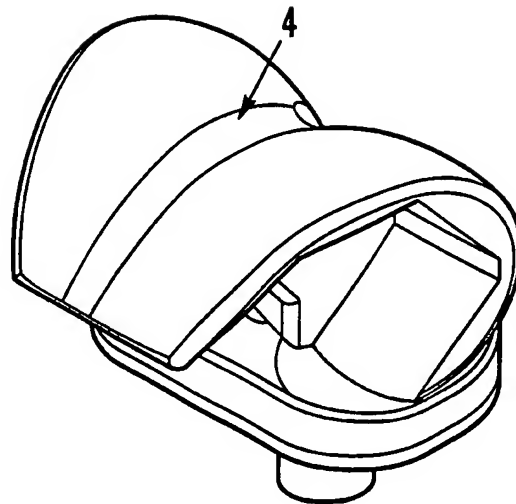


Fig. 3A

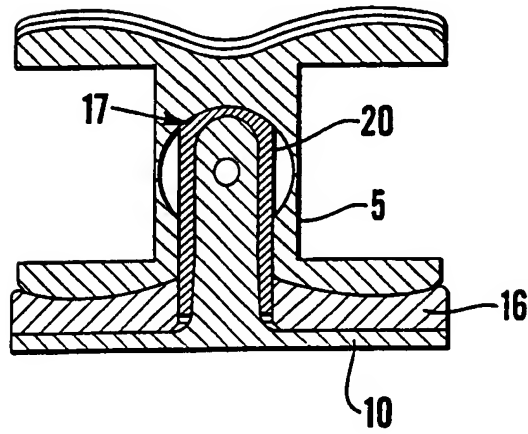


Fig. 3B

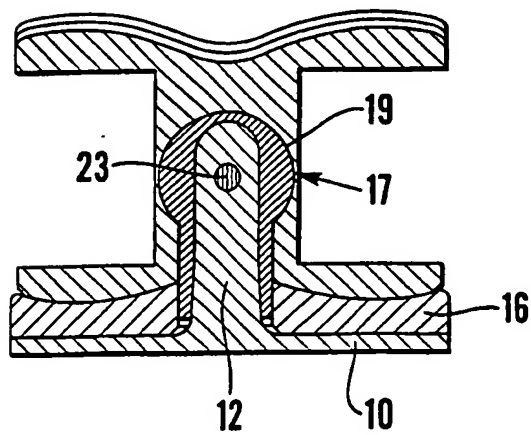


Fig. 3C

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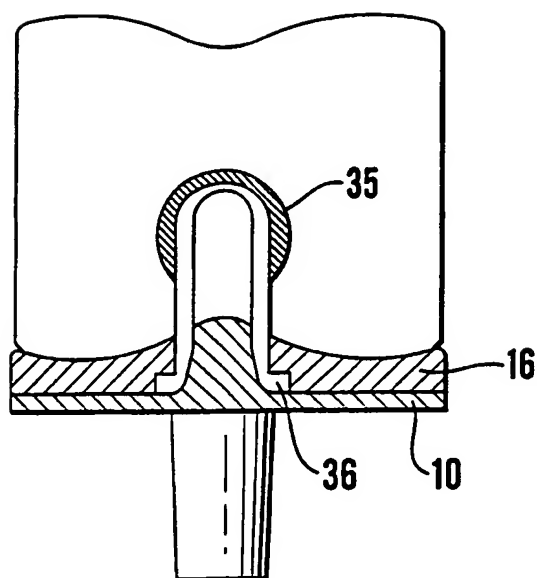


Fig. 4A

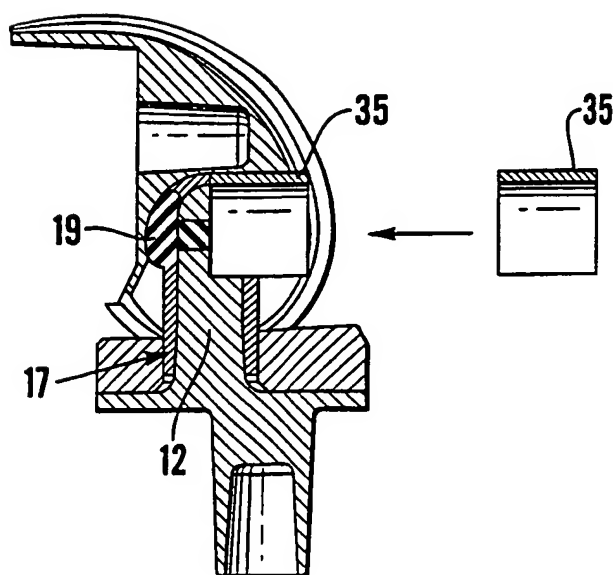


Fig. 4B

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GB 00/03259

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/38

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 3 868 730 A (KAUFER HERBERT ET AL) 4 March 1975 (1975-03-04) column 2, line 40 -column 4, line 43; figures 1-5	1-3,9,10
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

Internat'l Application No

PCT/GB 00/03259

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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